

## REMARKS

### *Status of Claims*

Claims 1-26 were original in the application. Claims 1-13 and 23-25 have been withdrawn. Claims 15 and 20 have been cancelled without prejudice. Claims 14, 17-19 21 and 22 have been currently amended. Claims 14, 16 – 19 and 21 - 26 are submitted for examination on the merits.

### *Rejection Pursuant to 35 USC 102*

In the latest office action, the Examiner rejected claims 14 and 17 as anticipated by U.S. Patent 7,188,628 ("Shubert"). The Examiner contended that Shubert disclosed the current invention as claimed including a method of oscillating a high speed burr including the steps of providing a motor source, connecting the motive source via a drive shaft assembly, oscillating the burr over a portion of a full circle at a rate effective for cutting hard matter while leaving softer tissue unharmed, providing a burr that is unshielded and fully exposed allowing the cutting to take place in all directions, and converting rotary motion to an oscillating motion. The applicant respectfully disagrees.

Shubert is acknowledged as showing oscillating an abrasive disk through a portion of a single rotation, i.e. between 5 and 180° (col. 5, line 67 – col. 6, line 1), with the result that a finger nail is abraded without alleged physical damage to adjacent skin. However, these teachings do not extend far enough to anticipate the claimed limitations of amended claim 14.

Claim 14 as amended is directed to a method of oscillating, a high speed surgical on-axis burr comprising providing a motive source with a driving axis, where the motive source is connected to the burr via a drive shaft assembly which is aligned along the driving axis, such as by the drive shaft assembly of the embodiment of Fig. 3. The driving pin 24 and caps 37, 38 of Fig. 3 are accurately on center. The oscillating burr is centered along the driving axis and is driven with minimal oscillation of the drive shaft assembly in a direction transverse to the driving axis at a oscillatory rate of 5000 Hz or greater over a portion of a full revolution of 180° or more to provide a stable oscillatory motion of the burr precisely on the driving axis. There is little to no side-to-side vibration in the claimed method.

Unlike trimming finger nails, the rotary action of a surgical burr must be precise. The method of the claim is used for spinal surgery in which application the finger nail trimmer of Shubert cannot be used because of its lack of precision as illustrated by abrasive disk motions shown in Figs. 7B and 7C. Use of a finger nail trimmer in spinal surgery would likely cause mayhem and malpractice. Further, such off-center inertia components in Shubert's trimmer become unacceptably exaggerated and unusable at the high rotational speeds of 5000 Hz and higher required by the claimed surgical application. No rotary speed is disclosed in Shubert, but conventional burring tools are operated at 3000 Hz or lower.

In regard to claim 17 as amended it is incorrect to characterize Shubert's cylinder flat faced, two dimensional disk 600 as a burr which is unshielded and fully exposed in the operational theater in three dimensions, and cutting with the burr virtually all directions without substantial impediment. Clearly, disk 600 can only be accessed in

a single normal direction and is accessible in any direction only from a hemisphere of origins and not a spherical domain of origins.

Additionally, the oscillating burr of the current application is a three-dimensional object. Paragraph 34 of the current application states that the burr is “a spherical or ball burring head having a cutting or abrading surface on nearly the full spherical surface, except for the area connected to drive shaft 24.” This means that, unlike the oscillating disc of Shubert, the current invention is capable of cutting several surfaces at once such as when the burr is positioned into a crevice or between two objects that require symmetrical cutting. Claim 17 has also been amended to state that the unshielded burr is fully exposed in the operational theater in three dimensions. It cannot be sustained that Shubert discloses each and every element of claims 14 and 17.

In summary, the apparatus disclosed in Shubert does not anticipate the current invention because the current apparatus is a precise surgical tool that oscillates a three dimensional burr capable of cutting or abrading bone or other similarly hard matter in three dimensions at very high frequencies with a lower limit of 5 kHz. In direct contrast, the apparatus disclosed by Shubert is a general tool for wearing down the nails of infants by oscillating a flat disk in two dimensions at comparatively low frequencies. In addition, the apparatus of Shubert would not be suitable for delicate surgery where bone needs to be cut. Therefore for these reasons, the claimed invention has not been described in a patent granted on an application for patent by another and the rejection should be withdrawn.

*Rejection Pursuant to 35 USC 103(a)*

In the latest office action, the Examiner rejected claims 16 and 18 as being obvious over Shubert in view of U.S. Patent 5,913,867 ("Dion"). The Examiner contended that Shubert discloses the invention substantially as claimed except for the oscillatory rate and the cooling, clearing, and removing of debris limitations of current claims 16 and 18. The Examiner further contended that Dion teaches a method of oscillating a high speed surgical burr and a method of cooling, clearing, and removing debris by suction and that when Shubert and Dion are viewed together, they render the current invention obvious. The Applicant respectfully disagrees.

Regarding claim 16, the Examiner states that it would have been obvious to one skilled in the art to take the device disclosed in Shubert and then change the motor in order to produce higher rotation speeds such as those disclosed in Dion. As the Examiner readily admits, the burr oscillation rate disclosed by Dion is only between 100 and 5000 Hz. In direct contrast, the current invention is oscillated at a rate higher than 5 kHz and as disclosed in paragraph 13, preferably 10 kHz or higher which is at least double than what the cited prior art is preferably operated.

Simply replacing the motor of the device found in Shubert with a higher speed version in order to achieve the claimed oscillation rate is nonobvious because as the rotation rate increases, the magnitude of any off-center momentum of the entire device increases by the square of the angular rate of rotation making it increasingly hard to control and thus perform a precise cut. Therefore, to increase the rate of rotation to twice the maximum used in Dion as claimed in claim 16 actually teaches away from conventional understanding and practice. In the present case it took over

four years of intense experimentation before a design which is solidly stable was devised. Over 50 different designs were tried and modeled before the claimed solution became clear.

Regarding claim 18, while the Examiner is correct in stating that Dion discloses a method of cooling and clearing a burr by fluid irrigation and fluid and removing debris by suction, both Shubert and Dion fail to teach or suggest a method of oscillating a burr which is unshielded and fully exposed in the operational theater at a rate of 10 kHz or higher. Shubert, as discussed above, oscillates a flat, round disk at an undisclosed rate while Dion oscillates a burr at only a maximum of 5000 rpm and shields the burr as shown in Figs. 1 - 3. Dion teaches the use of a hood 13 which “partially surrounds one side of burr 18, to protect adjacent tissue from the cutting action of burr 18, while also exposing the opposite side (and distal tip 44) of burr 18 to the tissue that the surgeon desires to cut (col. 5, lines 56-59). This use of a hood is clearly a shield and denies the burr full access to the operational theater.

Claim 19 was also rejected for being obvious over Shubert in view of U.S. Patent 4,536,156 (“Cattin”). The Examiner contended that Shubert discloses the current invention substantially as claimed except for the use of a slip clutch, while Cattin discloses just such a limitation. The Applicant respectfully disagrees.

Regarding claim 19, while the Examiner is correct in pointing out that Cattin discloses the use of a slip clutch, both Shubert and Cattin, whether taken separately or together, fail to teach or suggest using a slip clutch as a rotation-to-oscillation converter. As the abstract of Cattin clearly states, the purpose of the friction rotary drive disclosed in Cattin is to rotate a dental tool and drive it into a dental canal.

Only if the tool becomes jammed in the dental canal does the clutch activate and allow the mandrel to slip relative to the tool thus preventing the tool from experiencing too much torque and breaking off in the dental canal. In other words, the slip clutch as disclosed in Cattin is used exclusively as a safety measure for preventing the dental tool from snapping off in the dental canal and not for the main function of the tool itself. It is also therefore conceivable that should the dental tool not get stuck in the dental canal at any point during the procedure, the slip clutch would not be used at all.

In direct contrast, the current invention continuously uses a resilient biased slip clutch during normal operation to convert the rotational motion of a friction transmission into an oscillatory motion needed by the burr in order to cut bone (see paragraph 16). Cattin does not teach or suggest at any point a slip clutch that constantly converts rotational motion into oscillatory motion while the apparatus is in use, nor is Cattin's slip clutch resiliently biased to automatically re-engage for transmission of rotary motion after the clutch slips. Claim 19 has been amended in order to stress this difference.

The Examiner also rejected claims 21 and 22 as being obvious over Shubert in view of U.S. Patent Application 2002/0007190 ("Wulfman"). The Examiner contended that Shubert discloses the current invention substantially as claimed except for the use of a telescoping drive shaft and driven shaft, while Wulfman discloses just such a limitation. The Applicant respectfully disagrees.

Regarding claims 21 and 22, the Examiner is correct in pointing out that Wulfman does disclose telescopically coupled driving and driven shafts, however a telescopic drive "shaft" is not what is meant by the language of current claims 21 and

22. As clearly depicted in Fig. 3 of the current application, it is the driving hub 36 and driven hub 38 that are telescopically coupled together, not the driving shaft 24 and driven or oscillating shaft 25. Paragraph 36 of the current application further states that “The primary engagement of driven hub 38 to driving hub 36 is by means of frictional engagement with each other by one or more interleaved arcs 40 where they are telescopically overlapped. Shaft 24 may be extended through or into a bore (not shown) defined in driving hub 36 into driven hub 38 for stability and centering, but without significant frictional engagement.” From these two examples it should be clear that what was originally meant by stating that the driving shaft and driven shaft were coupled together via a frictional telescoping engagement was that the hubs located on the ends of their respective shafts were the members that were telescopically engaged, and not the shafts themselves as is disclosed in Figs. 3 and 4 of Wulfman. Claims 21 and 22 have therefore been amended in order to make this distinction more readily apparent.

Finally, the Examiner rejected claim 26 as being obvious over Shubert in view of Dion. The Examiner contended that Shubert discloses the invention substantially as claimed except for the oscillatory rate and the cooling, clearing, and removing of debris limitations of current claims 16 and 18. The Examiner further contended that Dion teaches a method of oscillating a high speed surgical burr and a method of cooling, clearing, and removing debris by suction and that when Shubert and Dion are viewed together, they render the current invention obvious. The Applicant respectfully disagrees.

Claim 26 is distinguished from the prior art on the same grounds as claims 16 and 18 discussed above, which grounds are herein reinstated.

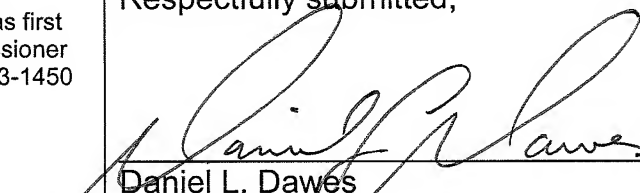
Applicant therefore respectfully requests advancement of the claims to allowance.

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